

ISO 13485
en

Agile Software Development

vrienden of vijanden?

Luciën Jaegers

MiPlaza

PHILIPS



ISO 13485
and

Agile Software Development

friend or foes?

Luciën Jaegers

MiPlaza

PHILIPS





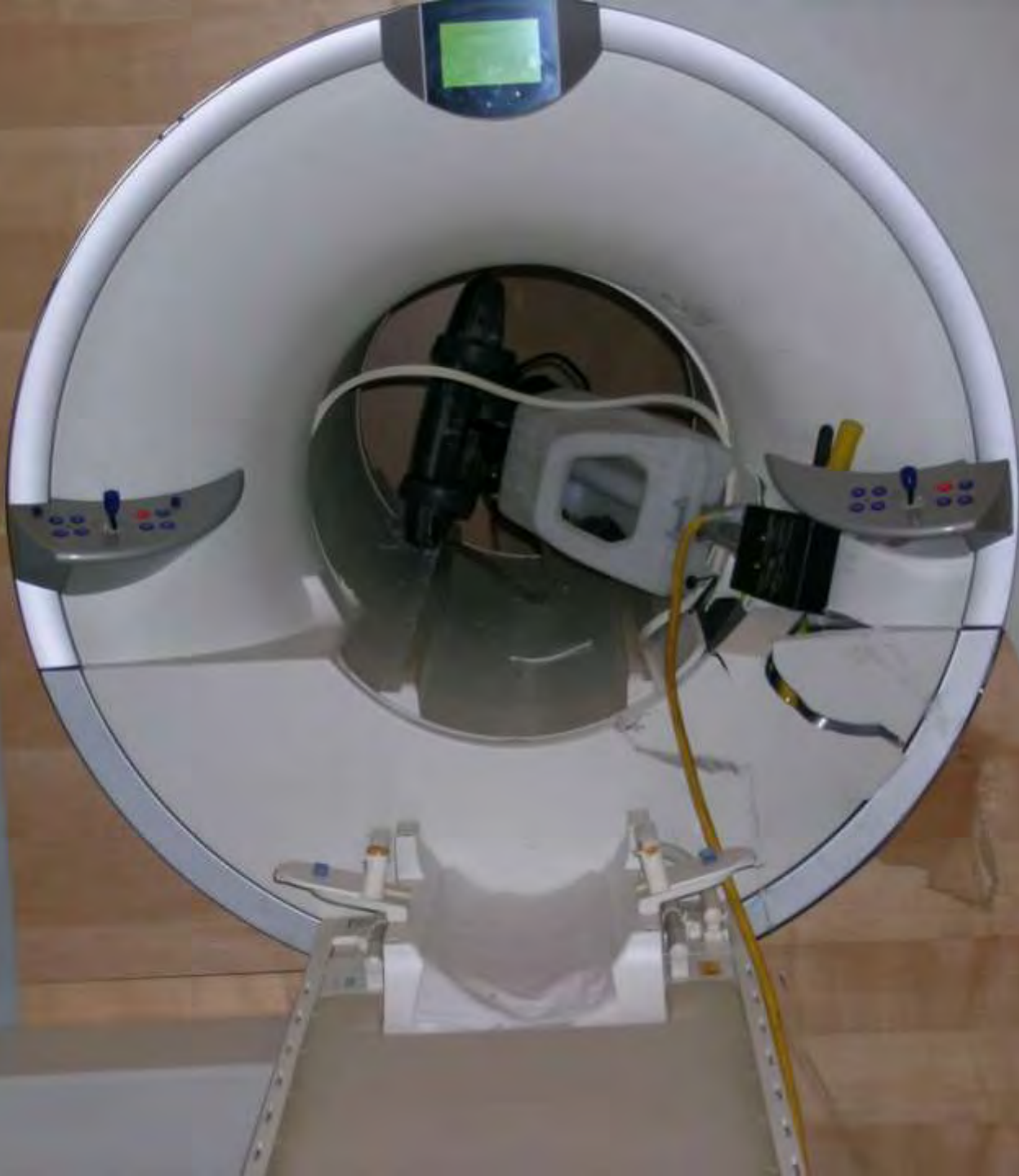
















Complexity



INTERNATIONAL STANDARD

ISO 13485

Second edition
2003-07-15

Medical devices — Quality management systems — Requirements for regulatory purposes

*Dispositifs médicaux — Systèmes de management de la qualité —
Exigences à des fins réglementaires*













American National Standard

ANSI/AAMI/IEC 62304:2006

**Medical device software—
Software life cycle processes**



What brings quality?



What brings quality?

Effectiveness

feedback

Usability

requirements

customer
involvement

system

simple
design

integration testing

planning

for safety

unit

documentation

clean code

hazard analysis

Maintainability

Safety











Manifesto for Agile Software Development

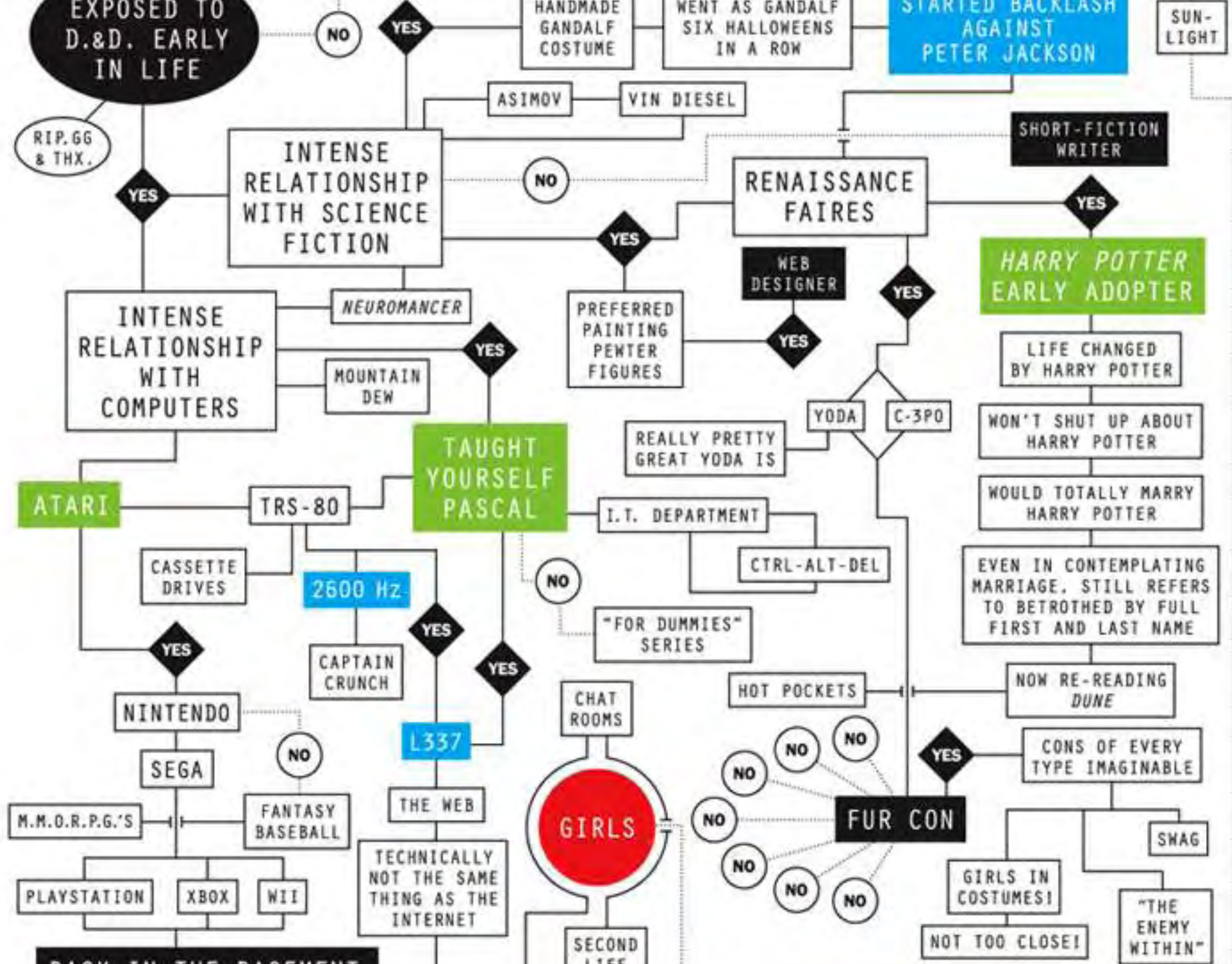
We are uncovering better ways of developing software by doing it and helping others do it.
Through this work we have come to value:

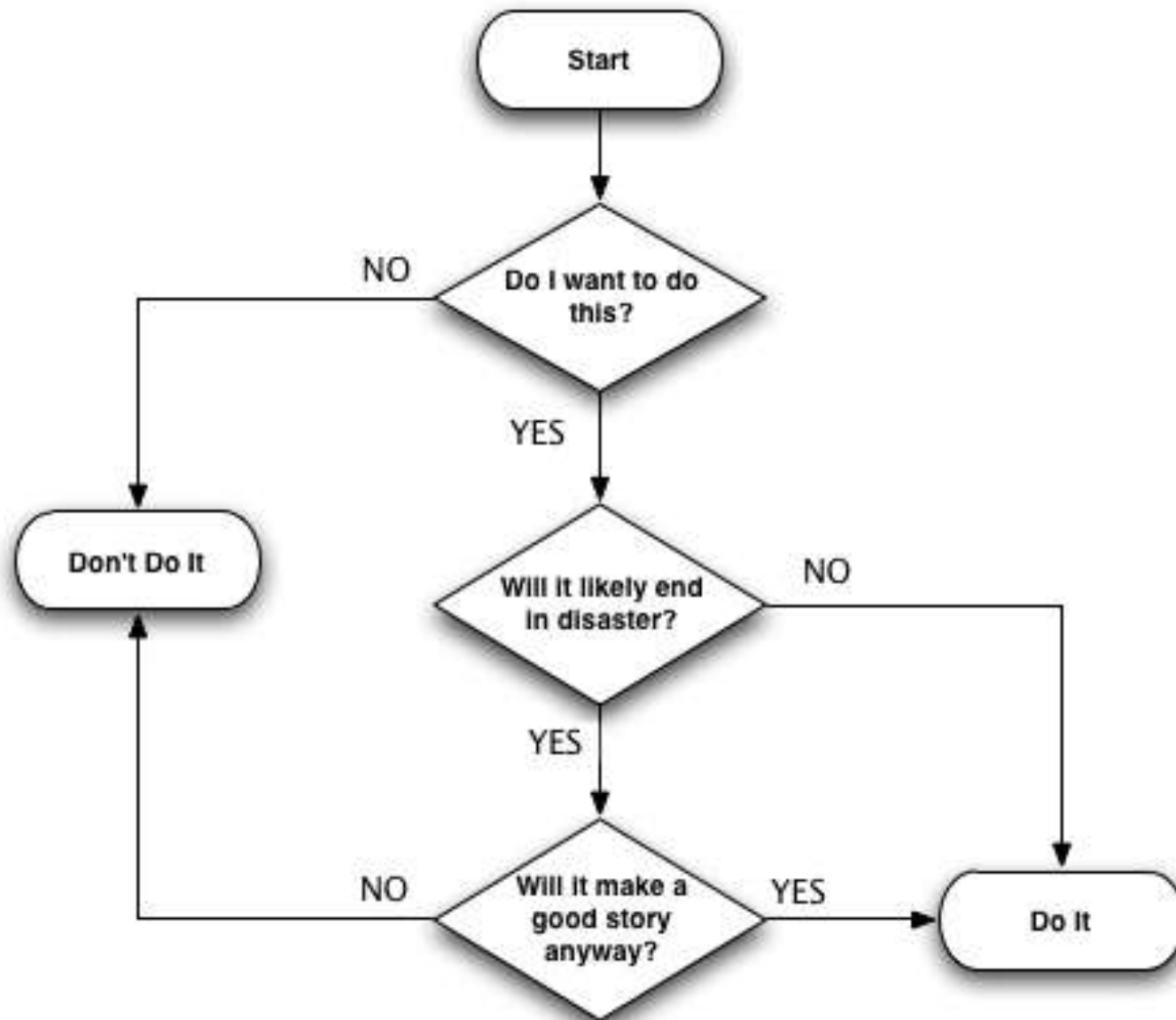
Individuals and interactions over **processes and tools**
Working software over **comprehensive documentation**
Customer collaboration over **contract negotiation**
Responding to change over **following a plan**

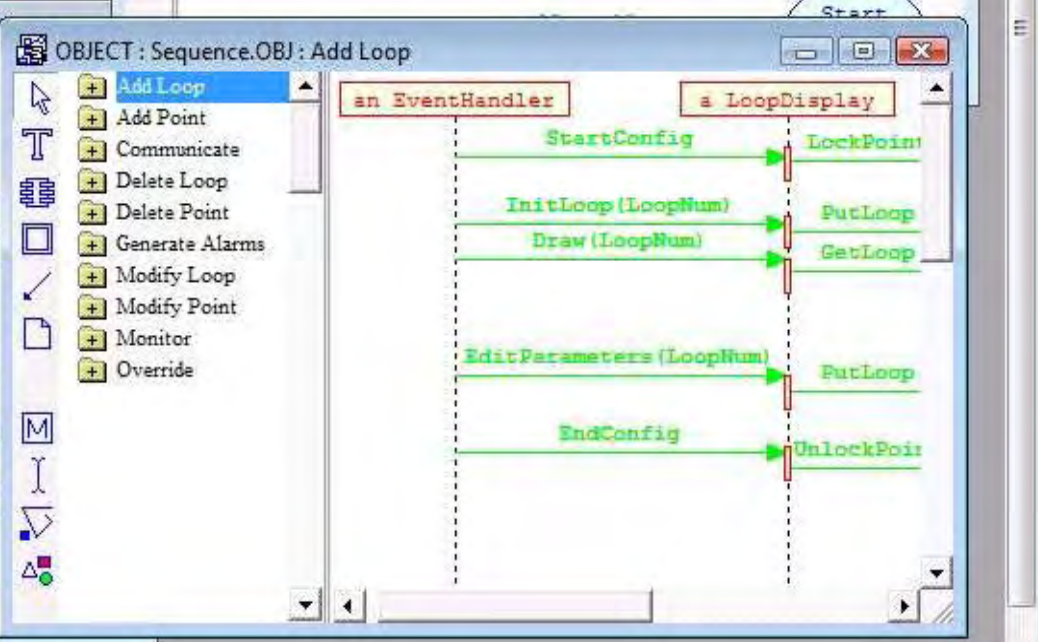
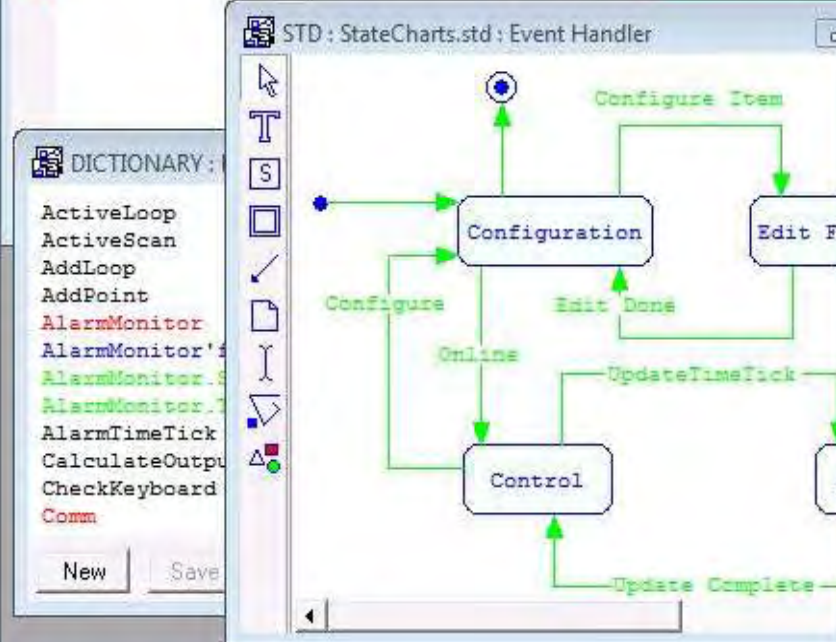
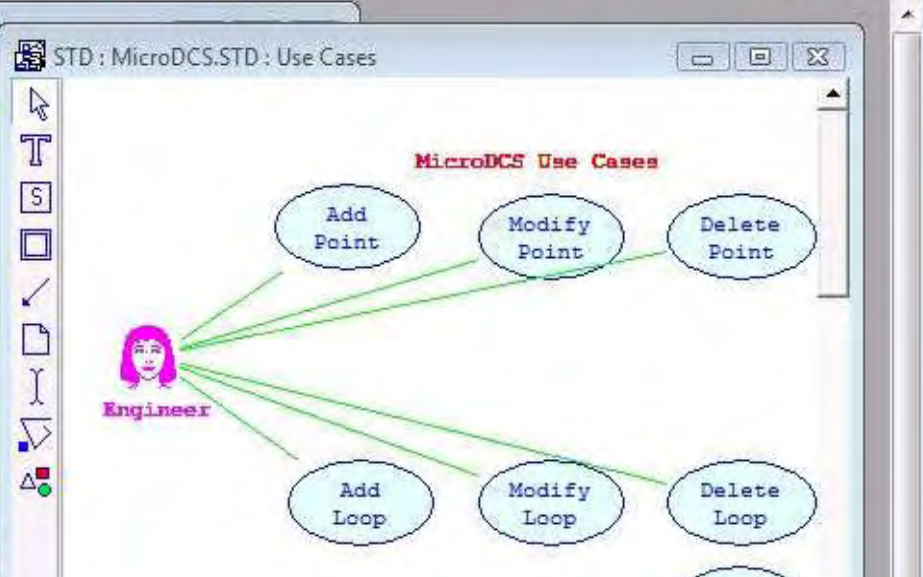
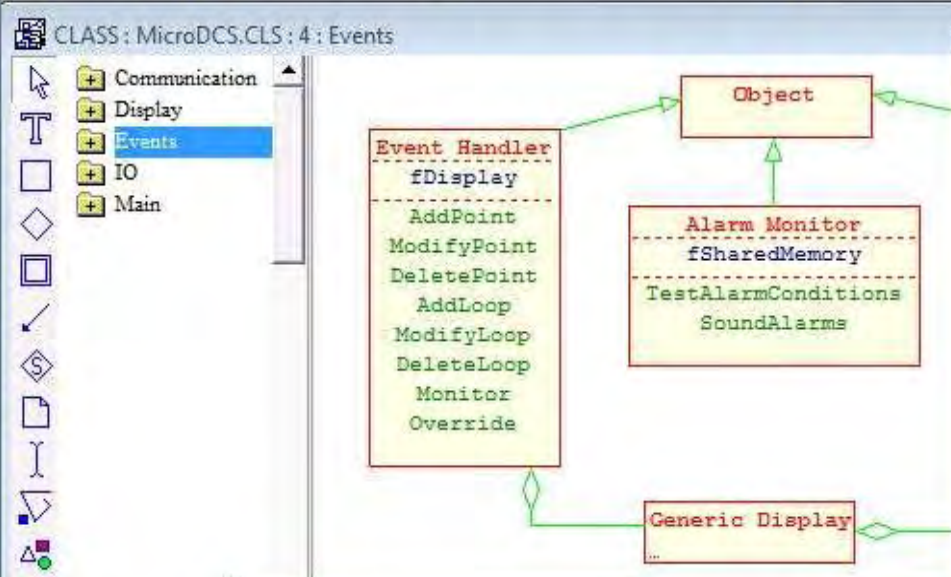
That is, while there is value in the items on the right,
we value the items on the left more.







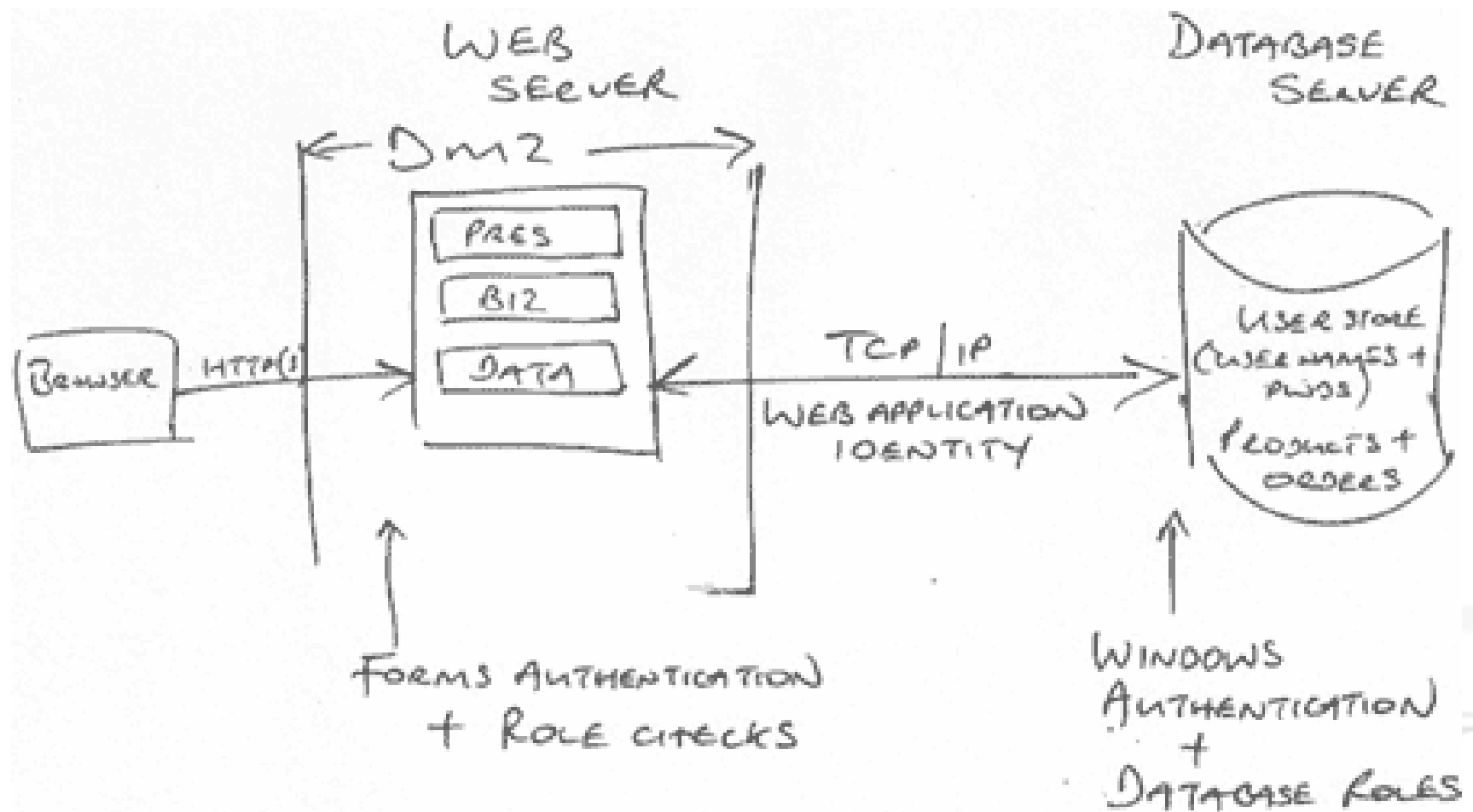


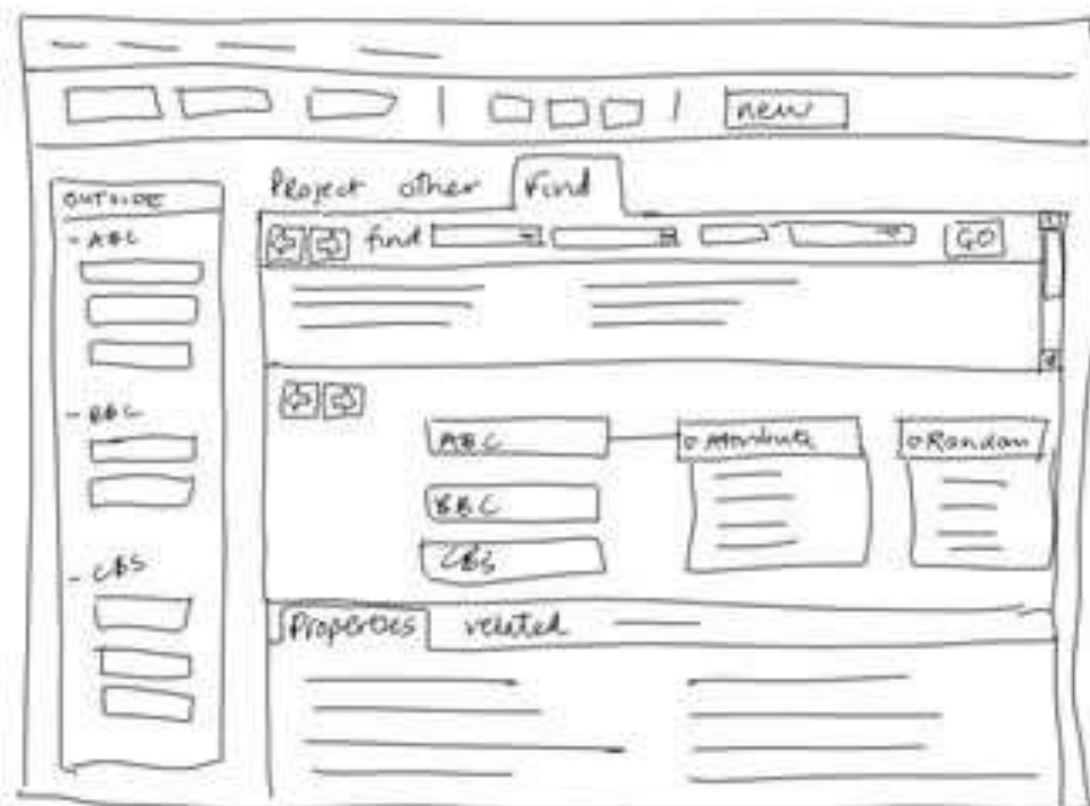


DICTIONARY :

- ActiveLoop
- ActiveScan
- AddLoop
- AddPoint
- AlarmMonitor
- AlarmMonitor'
- AlarmMonitor.S
- AlarmMonitor.T
- AlarmTimeTick
- CalculateOutput
- CheckKeyboard
- Comm

New Save







34411A
6½ Digit Multimeter

0.000000

V_{DC}

Sense
0.4W

Input
V_Ω Hz Δ



DCI

ACI

Ω 4W

Reset

Utility

Auto Rng

DCV

ACV

Ω 2W

2nd
Disp

Data
Log

Exit

eq

+

Temp

Math

Auto Trig

Local

Range +

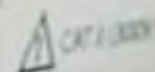


Range -

Front

Rear

Fused on
Rear Panel



CAT II 300V

Cont. (1)

Config

Null

Trigger

Shift



Regular documentation...

Product documentation

Project plan

Requirements specification

Architecture

Design

Verification specification

Verification report

Release notes

Installation Manual

User Manual

Additional documentation...

Evidence

Hazard Analysis report

Decisions

Records of measurements

Meeting minutes

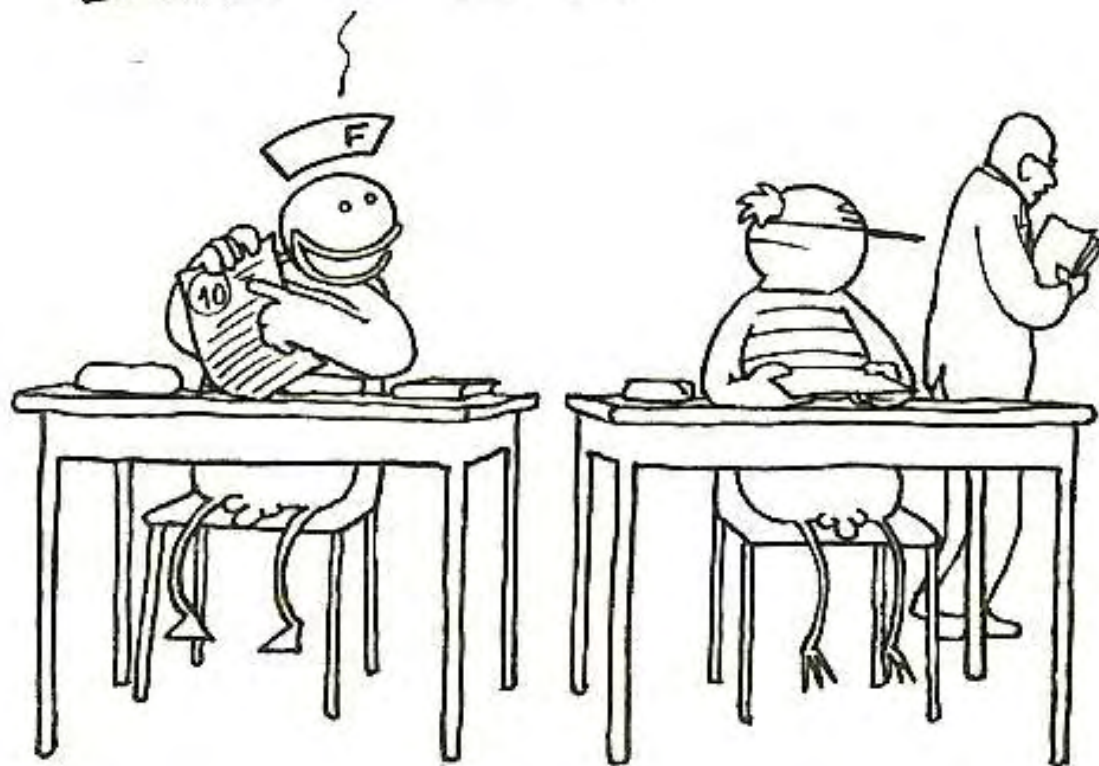
Competence matrix

FOKKE & SUKKE

HEBBEN EEN NIEUWE ONDERWIJSMETHODE ONTDEKT

ZÓ HEE!!

**DAT "LEREN"
DAT WERKT
ECHT GOED!!!**







Questions?



MiPlaza



**World-class expertise
Working for you**